

(b) An application for a continuation grant must be submitted for each funding period. This continuation application must include the following:

- (1) A budget and justification for the grant funds requested.
- (2) A summary of the progress achieved during the previous budget period.
- (3) A description of any changes in the information shown in the project application.

§ 51b.605 How will grant applications be evaluated and the grants awarded?

(a) Within the limits of funds available, the Secretary may award a grant to assist in meeting the costs of special activities authorized under section 318(b) of the Act.

(b) Grant applications will be reviewed and evaluated according to the following criteria:

(1) Is there adequate evidence that the proposed project is needed and that the outcome has potential to directly benefit the national venereal disease control effort?

(2) Are the project objectives specific, measurable, realistic, time phased, and related to promoting the purposes of section 318?

(3) Is the method of operation logical and clearly related to project objectives, and does it describe how the applicant intends to proceed particularly with activities which are complex, interrelated, or unprecedented?

(4) Does the method of operation include an assessment of any possible impact, both positive and negative, that the conduct of the proposed initiative might have upon the established venereal disease control program in the locality or localities in which the project will be undertaken?

(5) Does the proposal include a comprehensive and realistic plan for the evaluation of the project, and specify the measures and instruments of measurement to be used?

(6) Is the budget request reasonable and consistent with the intended use of grant funds?

(7) If the applicant intends only to evaluate an existing disease prevention and control approach, are the objectives substantially different from those

which could be met by routine program evaluation?

§ 51b.606 How can grant funds be used?

(a) Grant funds may be used for the costs associated with planning, organizing, and conducting applied research, demonstrations, and public information and education programs.

(b) Grant funds may also be used to reimburse individuals who agree to be participants in the applied research projects. This reimbursement, however, must be justified as necessary and reasonable. A schedule of reimbursements must be submitted with the application and approved as part of the program plan.

(c) Grant funds may not be used to supplant funds supporting existing venereal disease control services provided by a State or locality.

PART 51c—GRANTS FOR COMMUNITY HEALTH SERVICES

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AUTHORITY: Sec. 330, Public Health Service Act, 89 Stat. 342, (42 U.S.C. 254c); sec. 215, Public Health Service Act, 58 Stat. 690, (42 U.S.C. 216).

SOURCE: 41 FR 53205, Dec. 3, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 51c.101 Applicability.

The regulations of this subpart are applicable to all project grants authorized by section 330 of the Public Health Service Act (42 U.S.C. 254c).

§ 51c.102 Definitions.

As used in this part:

(a) *Act* means the Public Health Service Act.

(b) *Catchment area* means the area served by a project funded under section 330 of the Act.

(c)(1) *Community health center* or *center* means an entity which, through its staff and supporting resources or through contracts or cooperative arrangements with other public or private entities, provides for all residents of its catchment area:

- (i) Primary health services;
- (ii) As determined by the Secretary to be appropriate for particular centers, supplemental health services necessary for the adequate support of primary health services;
- (iii) Referral to providers of supplemental health services and payment, as determined by the Secretary to be appropriate and feasible, for their provision of such services;

(iv) Environmental health services, as determined by the Secretary to be appropriate for particular centers; and

(v) Information on the availability and proper use of health services.

(2) For purposes of paragraph (c)(1) of this section, the provision of a given service by a center will be determined by the Secretary to be appropriate where:

(i) There is a need, as determined by the Secretary, for the provision of such service in the catchment area; and

(ii) The provision of such service by the center is feasible, taking into consideration the center's projected revenues, other resources, and grant support under this part.

(d) *Environmental health services* means the detection and alleviation of unhealthful conditions of the environment of the catchment area, such as problems associated with water supply, sewage treatment, solid waste disposal, rodent and parasite infestation, and housing conditions. For the purposes of this part, the detection and alleviation of unhealthful conditions of the environment includes the notification of and making of arrangements with appropriate Federal, State, or local authorities responsible for correcting such conditions.

(e) *Medically underserved population* means the population of an urban or rural area designated by the Secretary as an area with a shortage of personal health services or a population group designated by the Secretary as having a shortage of such services. Medically underserved areas will be designated by the Secretary and a list of those designated will be published in the FEDERAL REGISTER from time to time, taking into consideration the following factors, among others:

(1) Available health resources in relation to size of the area and its population, including appropriate ratios of primary care physicians in general or family practice, internal medicine, pediatrics, or obstetrics and gynecology to population;

(2) Health indices for the population of the area, such as infant mortality rate;

(3) Economic factors affecting the population's access to health services, such as percentage of the population

with incomes below the poverty level; and

(4) Demographic factors affecting the population's need and demand for health services, such as percentage of the population age 65 and over.

(f) *Nonprofit*, as applied to any private agency, institution, or organization, means one which is a corporation or association, or is owned and operated by one or more corporations or associations, no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

(g) *Physician* means a licensed doctor of medicine or doctor of osteopathy.

(h) *Primary health services* means:

(1) Diagnostic, treatment, consultative, referral, and other services rendered by physicians, and, where feasible, by physician's extenders, such as physicians' assistants, nurse clinicians, and nurse practitioners;

(2) Diagnostic laboratory services and diagnostic radiologic services;

(3) Preventive health services, including medical social services, nutritional assessment and referral, preventive health education, children's eye and ear examinations, prenatal and post-partum care, prenatal services, well child care (including periodic screening), immunizations, and voluntary family planning services;

(4) Emergency medical services, including provision, through clearly defined arrangements, for access of users of the center to health care for medical emergencies during and after the center's regularly scheduled hours;

(5) Transportation services as needed for adequate patient care, sufficient so that residents of the catchment area served by the center with special difficulties of access to services provided by the center receive such services; and

(6) Preventive dental services provided by a licensed dentist or other qualified personnel, including (i) oral hygiene instruction; (ii) oral prophylaxis, as necessary; and (iii) topical application of fluorides, and the prescription of fluorides for systemic use when not available in the community water supply.

(i) *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the De-

partment of Health and Human Services to whom the authority involved has been delegated.

(j) *Supplemental health services* means health services which are not included as primary health services and which are:

(1) Inpatient and outpatient hospital services;

(2) Home health services;

(3) Extended care facility services;

(4) Rehabilitative services (including physical and occupational therapy) and long-term physical medicine;

(5) Mental health services, including services of psychiatrists, psychologists, and other appropriate mental health professionals;

(6) Dental services other than those provided as primary health services;

(7) Vision services, including routine eye and vision examinations and provision of eyeglasses, as appropriate and feasible;

(8) Allied health services;

(9) Pharmaceutical services, including the provision of prescription drugs;

(10) Therapeutic radiologic services;

(11) Public health services (including nutrition education and social services);

(12) Ambulatory surgical services;

(13) Health education services; and

(14) Services, including the services of outreach workers, which promote and facilitate optimal use of primary health services and services referred to in the preceding subparagraphs of this paragraph and, if a substantial number of individuals in the population served by the center are of limited English-speaking ability, the services of outreach workers and other personnel fluent in the language or languages spoken by such individuals.

§51c.103 Eligibility.

Any public or nonprofit private entity is eligible to apply for a grant under this part.

§51c.104 Application.

(a) An application for a grant under this part shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe.

(b) The application shall contain a budget and narrative plan of the manner in which the applicant intends to conduct the project and carry out the requirements of this part. The application must describe how and the extent to which the project has met, or plans to meet, each of the requirements in subpart B (relating to grants for planning and developing community health centers), subpart C (relating to grants for the operation of community health centers), or subpart D (relating to grants for the operation of community health projects), as applicable. In addition, applications must include:

(1) A statement of specific, measurable objectives and the methods to be used to assess the achievement of the objectives in specified time periods and at least on an annual basis.

(2) The precise boundaries of the catchment area to be served by the applicant, including an identification of the medically underserved population or populations within the catchment area. In addition, the application shall include information sufficient to enable the Secretary to determine that the applicant's catchment area meets the following criteria:

(i) The size of such area is such that the services to be provided by the applicant are available and accessible to the residents of the area promptly and as appropriate;

(ii) The boundaries of such area conform, to the extent practicable, to relevant boundaries of political subdivisions, school districts, and areas served by Federal and State health and social service programs; and

(iii) The boundaries of such area eliminate, to the extent possible, barriers resulting from the area's physical characteristics, its residential patterns, its economic and social groupings, and available transportation.

(3) The results of an assessment of the need that the population served or proposed to be served has for the services to be provided by the project (or in the case of applications for planning and development projects, the methods to be used in assessing such need), utilizing, but not limited to, the factors set forth in §51c.102(e)(1)-(4).

(4) Position descriptions for key personnel who will be utilized in carrying out the activities of the project and a statement indicating the need for the positions to be supported with grant funds to accomplish the objectives of the project.

(5) Letters and other forms of evidence showing that efforts have been made to secure financial and professional assistance and support for the project within the proposed catchment area and the continuing involvement of the community in the development and operation of the project.

(6) An assurance that an independent certified public accountant, or a public accountant licensed before December 31, 1970, will be engaged to certify that the system for the management and control of its financial assets will be in accord with sound financial management practices, including applicable Federal requirements.

(7) A list of all services proposed to be provided by the project.

(8) A list of services which are to be provided directly by the project through its own staff and resources and a description of any contractual or other arrangements (including copies of documents, where available) entered into, or planned for the provision of services.

(9) The schedule of fees and/or payments and schedule of discounts for services provided by the project.

(10) Evidence that all applicable requirements for review and/or approval of the application under title XV of the Act have been met.

(11) An assurance that the project will be conducted in accordance with the applicable requirements of this part.

(c) The application must be executed by an individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the statute, the applicable regulations of this part, and any additional conditions of the grant.

(Sec. 330, Public Health Service Act, 89 Stat. 342, (42 U.S.C. 254c); sec. 215, Public Health Service Act, 58 Stat. 690, 67 Stat. 63 (42 U.S.C. 216))

[41 FR 53205, Dec. 3, 1976, as amended at 48 FR 29201, June 24, 1983; 48 FR 45558, Oct. 6, 1983]

§51c.105 Accord with health planning.

A grant may be made under this part only if the applicable requirements of title XV of the Act relating to review and approval by the appropriate health planning agencies have been met.

§51c.106 Amount of grant.

(a) The amount of any award under this part will be determined by the Secretary on the basis of his estimate of the sum necessary for a designated portion of direct project costs plus an additional amount for indirect costs, if any, which will be calculated by the Secretary either:

(1) On the basis of the estimate of the actual indirect costs reasonably related to the project; or

(2) On the basis of a percentage of all, or a portion of, the estimated direct costs of the project when there are reasonable assurances that the use of such percentage will not exceed the approximate actual indirect costs. Such award may include an estimated provisional amount for indirect costs or for designated direct costs (such as fringe benefit rates) subject to upward (within the limits of available funds) as well as downward adjustments to actual costs when the amount properly expended by the grantee for provisional items has been determined by the Secretary: *Provided, however,* That no grant shall be made for an amount in excess of the total cost found necessary by the Secretary to carry out the project.

(i) In determining the percentage of project costs to be borne by the grantee, factors which the Secretary will take into consideration will include the following:

(A) The ability of the grantee to finance its share of project costs from non-Federal sources;

(B) The need in the area served by the project for the services to be provided; and

(C) The extent to which the project will provide services in an innovative manner which the Secretary desires to stimulate in the interest of developing more effective health service delivery systems on a regional or national basis.

(ii) At any time after approval of an application under this part, the Sec-

retary may retroactively agree to a percentage of project costs to be borne by the grantee lower than that determined pursuant to paragraph (a)(2)(i) of this section where he finds that changed circumstances justify a smaller contribution.

(iii) In determining the grantee's share of project costs, costs borne by Federal grant funds, or costs used to match other Federal grants, may not be included except as otherwise provided by law or regulations.

(b) All grant awards shall be in writing, and shall set forth the amount of funds granted and the period for which support is recommended.

(c) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application.

§51c.107 Use of project funds.

(a) Any funds granted pursuant to this part, as well as other funds to be used in performance of the approved project, may be expended solely for carrying out the approved project in accordance with section 330 of the Act, the applicable regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in subpart Q of 45 CFR part 74.

(b) Project funds awarded under this part may be used for, but need not be limited to, the following:

(1) The costs of acquiring and modernizing existing buildings (including the costs of amortizing the principal of, and paying interest on, loans), but only in accordance with subpart E of this part and as approved in the grant award;

(2) The costs of obtaining technical assistance to develop and improve the management capability of the project, but only as approved by the Secretary;

(3) The reimbursement of members of the grantee's governing board, if any, for reasonable expenses actually incurred by reason of their participation in board activities;

§51c.108

(4) The reimbursement of governing board members for wages lost by reason of participation in the activities of such board if the member is from a family with an annual family income below \$10,000 or if the member is a single person with an annual income below \$7,000;

(5) The cost of delivering health services, including services rendered on a prepaid capitation basis, to residents of the project's catchment area within the following limitations: grant funds may be used to pay the full cost of project services to individuals and families with annual incomes at or below those set forth in the most recent "CSA Income Poverty Guidelines" (45 CFR 1060.2) issued by the Community Services Administration; and to pay the portion of the cost of services provided in accordance with the schedule of discounts which, under such schedule, is uncompensated; *Provided*, That (i) charges will be made to such individuals and families in accordance with §51c.303(f) of subpart C; (ii) reasonable effort shall be made to collect such charges under a billing and collections system; and (iii) the charge to grant funds shall exclude any amounts collected pursuant to paragraph (b)(5)(ii) of this section;

(6) The cost of insurance for medical emergency and out-of-area coverage;

(7) The cost of providing to the staff of the project training related to the provision of health services provided or to be provided by the project, and, to the staff and governing board, if any, training related to the management of an ambulatory care facility, consistent with the applicable requirements of 45 CFR part 74; and

(8) The cost of developing and maintaining a reserve fund where required by State law for prepaid health care plans.

(c) Prior approval by the Secretary of revisions of the budget and project plan is required whenever there is to be a significant change in the scope or nature of project activities.

§51c.108 Grant payments.

The Secretary shall from time to time make payments to a grantee of all or a portion of any grant award, either in advance or by way of reimbursement

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for expenses incurred or to be incurred, to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

§51c.109 Nondiscrimination.

(a) Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252, (42 U.S.C. 2000d et seq.)) and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of race, color, or national origin be excluded from participation, in be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary of Health and Human Services with the approval of the President (45 CFR part 80). In addition, no person shall, on the grounds of age, sex, creed, or marital status (unless otherwise medically indicated), be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity so receiving Federal financial assistance.

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

§51c.110 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about recipients of services shall be held confidential, and shall not be divulged without the individual's consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary or his designee with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which

does not identify particular individuals.

§ 51c.111 Publications and copyright.

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publications, films, or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, non-exclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so.

§ 51c.112 Grantee accountability.

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other funds, including funds derived from other grant awards. With respect to each approved project, the grantee shall account for the sum total of all amounts paid as well as other funds and in-kind contributions by presenting or otherwise making available evidence satisfactory to the Secretary of expenditure for direct and indirect costs meeting the requirements of this part: *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed-percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursable direct costs incurred.

(b) *Accounting for interest earned on grant funds.* Pursuant to section 203 of the Intergovernmental Cooperation Act of 1968 (42 U.S.C. 4213), a State will not be held accountable for interest earned on grant funds, pending their disbursement for grant purposes. A State, as defined in section 102 of the Intergovernmental Cooperation Act, means any one of the several States, the District of Columbia, Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State, but does not include the government of the political subdivisions of the State. All grantees

other than a State, as defined, must return all interest earned on grant funds to the Federal Government.

(c) *Grant closeout*—(1) *Date of final accounting.* A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) *Final settlement.* There shall be payable to the Federal Government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section;

(ii) Any credits for earned interest pursuant to paragraph (b) of this section;

(iii) Any other amounts due pursuant to subparts F, M, and O of 45 CFR part 74.

§ 51c.113 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this part to State and local governments as those terms are defined in subpart A of that part 74. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this part:

45 CFR PART 74

Subpart

- A General.
- B Cash depositories.
- C Bonding and insurance.
- D Retention and custodial requirements for records.
- F Grant-related income.
- G Matching and cost sharing.
- K Grant payment requirements.
- L Budget revision procedures.
- M Grant closeout, suspension, and termination.
- O Property.
- Q Cost principles.

Subpart B—Grants for Planning and Developing Community Health Centers

§ 51c.201 Applicability.

The regulations of this subpart, in addition to the regulations of subpart

§51c.202

A of this part, are applicable to grants awarded pursuant to section 330(c) of the Act for projects for planning and developing community health centers which will serve medically underserved populations.

§51c.202 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of §51c.104 of subpart A, contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of §51c.203.

§51c.203 Project elements.

A project for the planning and developing of a community health center supported under this subpart must:

(a) Prepare an assessment of the need of the population proposed to be served by the community health center for the services set forth in §51c.102(c)(1) of subpart A, with special attention to the need of the medically underserved population for such services. Such assessment of need shall, at a minimum, consider the factors listed in §51c.102(e)(1)–(4).

(b) Design a community health center program for such population, based on such assessment, which indicates in detail how the proposed community health center will fulfill the needs identified in the assessment prepared pursuant to paragraph (a) of this section and how it will meet the requirements contained in subpart C of this part.

(c) Develop a plan for the implementation of the program designed pursuant to paragraph (b) of this section. Such implementation plan shall provide for the time-phased recruitment and training of the personnel essential for the operation of a community health center and the gradual assumption of operational status of the project so that the project will, in the judgment of the Secretary, meet the requirements contained in subpart C of this part as of the end of the project period.

(d) Implement the plan developed pursuant to paragraph (c) of this sec-

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tion in accordance with such paragraph.

(e) Make efforts to secure, within the proposed catchment area of such center to the extent possible, financial and professional assistance and support for the project.

(f) Initiate and encourage continuing community involvement in the development and operation of the project.

(g) Establish standards and qualifications for personnel (including the project director).

(h) Utilize, to the maximum extent feasible, other Federal, State, local, and private resources available for support of the project, prior to use of project funds under this subpart.

§51c.204 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(c) of the Act and the applicable regulations of this part, taking into account:

(1) The degree to which the proposed project satisfactorily provides for the elements set forth in §51c.203;

(2) The relative need of the population to be served for the services to be provided;

(3) The administrative and management capability of the applicant;

(4) The potential of the project for development of new and effective methods for health services delivery and management;

(5) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(6) The extent to which community resources will be utilized in the project;

(7) The extent to which grants approved under this part will provide for an appropriate distribution of resources throughout the country, taking into consideration the following factors;

(i) The urban-rural area to be served;

(ii) The nature of the organization applying; and

(iii) The organizational structure for delivery of services;

(8) Whether the project's catchment area is exclusive of the area served by a community health center;

(9) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health services or reimbursement programs or projects.

(b) The Secretary may:

(1) Make no more than two grants under this subpart for the same project.

(2) Make a grant under this subpart to an entity which has been awarded one or more grants under section 330(d)(1)(A) and/or section 330(d)(1)(B) of the Act only if the grant under this subpart is for a new project.

Subpart C—Grants for Operating Community Health Centers

§ 51c.301 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A, are applicable to grants awarded pursuant to section 330(d)(1)(A) of the Act for the costs of operation of community health centers which serve medically underserved populations.

§ 51c.302 Application.

To be approved by the Secretary under this subpart, an application for a grant must, in addition to meeting the requirements of § 51c.104 of subpart A,

(a) Be submitted by an entity which may be a co-applicant which the Secretary determines is a community health center, and

(b) Contain information sufficient to enable the Secretary to determine that the center will meet the requirements of § 51c.103.

[41 FR 53205, Dec. 3, 1976, as amended at 42 FR 60418, Nov. 25, 1977]

§ 51c.303 Project elements.

A community health center supported under this subpart must:

(a) Provide the health services of the center so that such services are available and accessible promptly, as appropriate, and in a manner which will assure continuity of service to the residents of the center's catchment area.

(b) Implement a system for maintaining the confidentiality of patient records in accordance with the requirements of § 51c.110 of subpart A.

(c) Have an ongoing quality assurance program which provides for the following:

(1) Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care;

(2) Periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided to individuals served by the center. Such assessments shall:

(i) Be conducted by physicians or by other licensed health professionals under the supervision of physicians;

(ii) Be based on the systematic collection and evaluation of patient records; and

(iii) Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated.

(d) Develop management and control systems which are in accordance with sound financial management procedures, including the provision for an audit on an annual basis (unless waived for cause by the Secretary) by an independent certified public accountant or a public accountant licensed prior to December 31, 1970, to determine, at a minimum, the fiscal integrity of grant financial transactions and reports, and compliance with the regulations of this part and the terms and conditions of the grant.

(e) Where the cost of care and services furnished by or through the project is to be reimbursed under title XIX or title XX of the Social Security Act, obtain or make every reasonable effort to obtain a written agreement with the title XIX or title XX State agency for such reimbursement.

(f) Have prepared a schedule of fees or payments for the provision of its services designed to cover its reasonable costs of operation and a corresponding schedule of discounts adjusted on the basis of the patient's ability to pay. *Provided*, That such schedule of discounts shall provide for a full discount

to individuals and families with annual incomes at or below those set forth in the most recent CSA Poverty Income Guidelines (45 CFR 1060.2) and for no discount to individuals and families with annual incomes greater than twice those set forth in such Guidelines, except that nominal fees for services may be collected from individuals with annual incomes at or below such levels where imposition of such fees is consistent with project goals.

(g) Make every reasonable effort, including the establishment of systems for eligibility determination, billing, and collection, to:

(1) Collect reimbursement for its costs in providing health services to persons who are entitled to insurance benefits under title XVIII of the Social Security Act, to medical assistance under a State plan approved under title XIX of such Act, to social services and family planning under title XX of such Act, or to assistance for medical expenses under any other public assistance program, grant program, or private health insurance or benefit program on the basis of the schedule of fees prepared pursuant to paragraph (f) of this section without application of any discounts, and

(2) Secure from patients payments for services in accordance with the schedule of fees and discounts required by paragraph (f) of this section.

(h) Have a governing board which meets the requirements of §51c.304.

(i) Have developed an overall plan and budget for the center that:

(1) Provides for an annual operating budget and a three-year financial management plan which include all anticipated income and expenses related to items which would, under generally accepted accounting principles, be considered income and expense items;

(2) Provides for a capital expenditures plan for at least a three-year period (including the year to which the operating budget described in paragraph (i)(1) of this section is applicable) which includes and identifies in detail the anticipated sources of financing for, and the objective of, each anticipated expenditure in excess of \$100,000 related to the acquisition of land, the improvement of land, buildings, and equipment and the replace-

ment, modernization and expansion of buildings and equipment which would, under generally accepted accounting principles, be considered capital items;

(3) Provides for plan review and updating at least annually; and

(4) Is prepared under the direction of the governing board, by a committee consisting of representatives of the governing board, and administrative staff, and the medical staff, if any, of the center.

(j) Establish basic statistical data, cost accounting, management information, and reporting or monitoring systems which shall enable the center to provide such statistics and other information as the Secretary may reasonably require relating to the center's costs of operation, patterns of utilization of services, and the availability, accessibility, and acceptability of its services and to make such reports to the Secretary in a timely manner with such frequency as the Secretary may reasonably require.

(k) Review its catchment area annually to insure that the criteria set out in §51c.104(b)(2) of subpart A are met and, where such criteria are not met, revise its catchment area, with the approval of the Secretary, to conform to such criteria to the extent feasible.

(l) In the case of a center which serves a population including a substantial proportion of individuals of limited English-speaking ability, have developed a plan and made arrangements responsive to the needs of such populations for providing services to the extent practicable in the language and cultural context most appropriate to such individuals, and have identified an individual on its staff who is fluent in both that language and in English and whose responsibilities include providing guidance to such individuals and to appropriate staff members with respect to cultural sensitivities and bridging linguistic and cultural differences. If more than one non-English language is spoken by such group or groups, an individual or individuals fluent in those languages and English shall be so identified.

(m) Be operated in a manner calculated to preserve human dignity and to maximize acceptability and effective utilization of services.

(n) To the extent possible, coordinate and integrate project activities with the activities of other Federally funded, as well as State and local, health services delivery projects and programs serving the same population.

(o) Establish means for evaluating progress toward the achievement of the specific objectives of the project.

(p) Provide sufficient staff, qualified by training and experience, to carry out the activities of the center.

(q) Assure that facilities utilized in the performance of the project meet applicable fire and life safety codes.

(r) Utilize, to the maximum extent feasible, other Federal, State, and local, and private resources available for support of the project, prior to use of project funds under this part.

(s) Provide for community participation through, for example, contributions of cash or services, loans of full- or part-time staff, equipment, space, materials, or facilities.

(t) Where the center will provide services through contract or other cooperative arrangements with other providers of services, establish rates and methods of payment for health care. Such payments must be made pursuant to agreements, with a schedule of rates and payment procedures maintained by the project. The project must be prepared to substantiate that such rates are reasonable and necessary.

(u) Operate in a manner such that no person shall be denied service by reason of his inability to pay therefor: *Provided, however*, That a charge for the provision of services will be made to the extent that a third party (including a Government agency) is authorized or is under legal obligation to pay such charges.

(v) In addition to the above, projects which are supported with grant funds for the operation of a prepaid health care plan also must provide:

(1) A marketing and enrollment plan, including market analysis, marketing strategy, and enrollment growth projections.

(2) A plan that provides for funding on a capitation basis of such portion of the residents of the catchment area of the center, as the Secretary shall determine.

(3) An assurance that services shall be available to all residents of the catchment area without regard to method of payment or health status.

§51c.304 Governing board.

A governing board for the center shall be established by an applicant as follows:

(a) *Size*. The board shall consist of at least 9 but not more than 25 members, except that this requirement may be waived by the Secretary for good cause shown.

(b) *Composition*. (1) A majority of the board members shall be individuals who are or will be served by the center and who, as a group, represent the individuals being or to be served in terms of demographic factors, such as race, ethnicity, sex.

(2) No more than one-half of the remaining members of the board may be individuals who derive more than 10 percent of their annual income from the health care industry.

(3) The remaining members of the board shall be representative of the community in which the center's catchment area is located and shall be selected for their expertise in community affairs, local government, finance and banking, legal affairs, trade unions, and other commercial and industrial concerns, or social service agencies within the community.

(4) No member of the board shall be an employee of the center, or spouse or child, parent, brother or sister by blood or marriage of such an employee. The project director may be a non-voting, ex-officio member of the board.

(c) *Selection of members*. The method of selection of all governing board members shall be prescribed in the by-laws or other internal governing rules of the center. Such by-laws or other rules must specify a process of selection of individuals on the governing board who represent the population served or to be served by the center so that such individuals, as a group, are representative of such population. Such process of selection in the by-laws or other rules is subject to approval by the Secretary.

(d) *Functions and responsibilities*. (1) The governing board for the center

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shall have authority for the establishment of policy in the conduct of the center.

(2) The governing board shall hold regularly scheduled meetings, at least once each month, for which minutes shall be kept.

(3) The governing board shall have specific responsibility for:

(i) Approval for the selection and dismissal of a project director or chief executive officer of the center;

(ii) Establishing personnel policies and procedures, including selection and dismissal procedures, salary and benefit scales, employee grievance procedures, and equal opportunity practices;

(iii) Adopting policy for financial management practices, including a system to assure accountability for center resources, approval of the annual project budget, center priorities, eligibility for services including criteria for partial payment schedules, and long-range financial planning;

(iv) Evaluating center activities including services utilization patterns, productivity of the center, patient satisfaction, achievement of project objectives, and development of a process for hearing and resolving patient grievances;

(v) Assuring that the center is operated in compliance with applicable Federal, State, and local laws and regulations; and

(vi) Adopting health care policies including scope and availability of services, location and hours of services, and quality-of-care audit procedures.

§ 51c.305 Grant evaluation and award.

Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(d)(1)(A) of the Act and the applicable regulations of this part, taking into consideration;

(a) The extent to which the project would provide for the elements set forth in § 51c.303;

(b) The relative need of the population to be served for the services to be provided;

(c) The potential of the center for the development of new and effective

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methods for health services delivery and management;

(d) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(e) The administrative and management capability of the applicant;

(f) The extent to which grants approved under this part will provide for an appropriate distribution of resources throughout the country, taking into consideration the following factors:

(1) The urban-rural area to be served;

(2) The nature of the organization applying;

(3) The organizational structure for delivery of services;

(g) The number of users of the center and the level of utilization of services in previous operational periods, if any;

(h) Whether the center's catchment area is exclusive of the area served by another center;

(i) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health services or reimbursement programs or projects;

(j) The extent to which community resources will be utilized by the project;

(k) The extent to which the center will provide preventive health services so as to maintain and improve the health status of the population served; and

(l) The extent to which center operations will emphasize direct health services, efficiency of operations and sound financial management.

Subpart D—Grants for Operating Community Health Projects

§ 51c.401 Applicability.

The regulations of this subpart, in addition to the regulations of subpart A are applicable to grants awarded pursuant to section 330(d)(1)(B) of the Act for the costs of operation of projects which provide health services to medically underserved populations.

§ 51c.402 Application.

To be approved by the Secretary under this subpart, an application for a

grant must, in addition to meeting the requirements of § 51c.104 of subpart A, contain information sufficient to enable the Secretary to determine that the project for which the grant is sought will meet the requirements of § 51c.403 of this subpart.

§ 51c.403 Project elements.

A project for the operation of a community health project supported under this subpart must:

(a) Meet all of the requirements of § 51c.303 of this part except for paragraph (h).

(b) Provide those services enumerated in § 51c.102(c)(1) of this part which the Secretary determines to be feasible and desirable and which are specified in the grant award.

(c) Establish a governing board meeting the requirements of § 51c.304 by the end of the period of support under section 330(d)(1)(B) of the Act and this subpart.

§ 51c.404 Grant evaluation and award.

(a) Within the limits of funds determined by the Secretary to be available for such purpose, the Secretary may award grants under this subpart to applicants therefor which will, in his judgment, best promote the purposes of section 330(d)(1)(B) of the Act and the applicable regulations of this part.

(1) Where the project meets the requirements of § 51c.403(a); and

(2) Taking into consideration the following:

(i) The degree to which the project would provide the services enumerated in § 51c.102(c)(1) and the feasibility of its providing all of such enumerated services by the end of the period of support under section 330(d)(1)(B) of the Act and this subpart;

(ii) Whether the project will have a governing board meeting the requirements of § 51c.304 by the end of the period of support under section 330(d)(1)(B) of the Act and this subpart;

(iii) The degree to which the applicant intends to integrate services supported by a grant under this subpart with health services provided under other Federally assisted health service or reimbursement programs or projects;

(iv) The need of the population to be served for the services to be provided;

(v) The potential of the project for the development of new and effective methods for health services delivery and management;

(vi) The soundness of the fiscal plan for assuring effective utilization of grant funds and maximizing non-grant revenue;

(vii) The administrative and management capacity of the applicant; and

(viii) The extent to which community resources will be utilized in the project.

(b) The Secretary may:

(1) Make no more than two grants for the same entity under section 330(d)(1)(B) of the Act;

(2) Not make any grant under section 330(d)(1)(B) to an entity which, for the same project, has been awarded more than one grant under section 330(c) of the Act;

(3) Not make a grant under section 330(d)(1)(B) to an entity which has been awarded a grant under section 330(d)(1)(A) of the Act.

Subpart E—Acquisition and Modernization of Existing Buildings

§ 51c.501 Applicability.

The regulations of this subpart, in addition to the regulations of the other applicable subparts of this part, are applicable to grants under section 330 of the Act for project costs which include the cost of acquisition and/or modernization of existing buildings (including the cost of amortizing the principal of, and paying the interest on, loans), except that, these regulations are not applicable to grants for project costs which include the costs of modernization of existing buildings if those costs can otherwise be supported under subparts B, C, or D of this part.

[43 FR 5352, Feb. 7, 1978]

§ 51c.502 Definitions.

(a) *Equipment* means nonexpendable personal property as defined in 45 CFR 74.132.

(b) *Existing building* means a completed or substantially completed structure, and may include the realty on which it is or is to be located.

(c) *Modernization* means the alteration, repair, remodeling and/or renovation of a building (including the initial equipment thereof and improvements to the building's site) which, when completed, will render the building suitable for use by the project for which the grant is made.

[43 FR 5352, Feb. 7, 1978]

§ 51c.503 Application.

(a) *General requirements.* An application for a grant under this part for a project under subparts B, C, or D which includes the acquisition and/or modernization of an existing building must include the following:

(1) A legal description of the site and a drawing showing the location of the building;

(2) A description of the architectural, structural, and other pertinent characteristics of the building sufficient to show that it is or that it will be, after alteration and renovation or after modernization, suitable for use by the project;

(3) A detailed estimate of the cost of the proposed acquisition and/or modernization;

(4) A description of, and copies of any relevant documents concerning, any existing or proposed financing arrangements for the acquisition and/or modernization;

(5) The proposed schedule for acquisition and/or modernization and occupancy;

(6) An assessment of the environmental impact of the proposed acquisition and/or modernization as called for by section 102(2)(c) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(c)) and such information as may be necessary to comply with the National Historic Preservation Act of 1966 (16 U.S.C. 470(f));

(7) Reasonable assurances that—

(i) The applicant has or will obtain a fee simple or such other estate or interest in the site, including necessary easements and rights-of-way, sufficient to assure for a period of not less than 20 years (in the case of interim facilities, for the period constituting the estimated useful life of such facilities) undisturbed use and possession for the purpose of the operation of the project;

(ii) The building will be used for the purposes for which the grant is made;

(iii) The building complies, or after alteration and renovation or after modernization will comply, with applicable State and local codes and with:

(A) "American National Standard Specifications for Making Buildings and Facilities Accessible to, and Usable by, the Physically Handicapped" Number ANSI A117.1-1961 (R 1971), as modified by other standards prescribed by the Secretary or the Administrator of the General Services Administration. The applicant shall be responsible for conducting inspections to insure compliance with the specifications;

(B) The applicable standards set forth in Life Safety Code 1973, NFPA No. 101, which is hereby incorporated by reference and made a part hereof. Copies of such document are available for examination at the Department's and Regional Offices' Information Centers listed in 45 CFR 5.31 and may also be obtained from the National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210 for \$3.00 per copy.

(iv) In the case of a public applicant with an approved project which involves the displacement of persons or businesses on or after January 2, 1971, whose real property has or will be taken, the applicant will comply with the provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (Pub. L. 91-646) and the applicable regulations issued thereunder (45 CFR part 15);

(v) Sufficient funds will be available to meet any portion of the cost of acquiring and/or modernizing the building not borne by the grant under this part;

(vi) Sufficient funds will be available after acquisition and/or modernization of the building for effective use of the building for the purposes of the project;

(vii) The applicable requirements of the Flood Disaster Protection Act of 1973 have been met;

(8) Such other information as the Secretary may reasonably require.

(b) *Requirement for acquisition grants.* Except for a grant solely for amortization of principal and payment of interest on an existing loan, an application for a grant for a project which includes

the acquisition of an existing building must include, in addition to the requirements of paragraph (a) of this section, evidence satisfactory to the Secretary that the applicant has explored other alternatives to the proposed acquisition (such as leasing facilities or acquiring other facilities in the project's catchment area) and that the proposed acquisition constitutes the soundest alternative from a financial and program standpoint.

(c) *Requirements for modernization grants.* In addition to the requirements of paragraph (a) of this section, an application for a grant for a project which includes modernization of an existing building must include the following:

(1) Plans and specifications for the proposed modernization which conform to the standards specified in §51c.503(a)(7)(iii);

(2) Reasonable assurance that any laborer or mechanic employed by any contractor or subcontractor in the performance of work on the modernization project will be paid wages at rates not less than those prevailing on similar work in the locality as determined by the Secretary of Labor under the Davis-Bacon Act (40 U.S.C. 276a *et seq.*) and will receive compensation at a rate not less than one and one-half times his basic rate of pay for all hours worked in any workweek in excess of 8 hours in any calendar day; and

(3) Copies of any construction and materials contracts already entered into for the proposed modernization.

[41 FR 57000, Dec. 30, 1976, as amended at 43 FR 5352, Feb. 7, 1978]

§51c.504 Project elements.

(a) *General requirements.* A grantee which has received a grant under section 330 of the Act for a project which includes the acquisition and/or modernization of an existing building must:

(1) *Assurances.* Comply with the assurances provided pursuant to this subpart.

(2) *Approval of estimated cost.* Not enter into any contract for the acquisition and/or modernization funded under this subpart where the cost of such acquisition and/or modernization exceeds the estimates in the application, without the prior approval of the Secretary.

(3) *Non-default.* Make every effort to prevent any default on any loan secured by the building and, in the event of a default, promptly notify the Secretary of the default and make every effort on a timely basis to cure the default.

(b) *Requirements for acquisition grants.* In addition to the requirements of paragraph (a) of this section, a grantee which has received a grant under section 330 of the Act for a project which includes the acquisition of an existing building must:

(1) *Bona-fide sale.* Acquire or, in the case of a grant solely for amortization of principal and payment of interest on an existing loan, have acquired the existing building pursuant to a bona-fide sale involving an actual cost to the applicant and resulting in additional or improved facilities for the purposes of the project.

(2) *Standards of construction and equipment.* Except in the case of a grant solely for amortization of principal and payment of interest on an existing loan, obtain a determination by the Secretary that the facility conforms (or upon completion of any necessary alteration and renovation or modernization will conform) to the standards set forth in §51c.503(a)(7)(iii) of this subpart before entering into a final or unconditional contract for the acquisition. Where the Secretary finds that exceptions to or modifications of any such standards would be consistent with the purposes of the Act and of the program, he may authorize such exceptions or modifications.

(3) *Financing.* Where the grantee will obtain a loan secured by the building in order to acquire the building, obtain such financing at the lowest current rate prevailing in the area for comparable loans on comparable facilities.

(c) *Requirements for modernization grants.* In addition to the requirements of paragraph (a) of this section, a grantee which has received a grant under section 330 of the Act for a project which includes the modernization of an existing building must:

(1) *Costs in excess of approved costs.* Finance all costs in excess of the estimated costs approved in the application and submit to the Secretary for

prior approval any changes that substantially alter the scope of the function, utilities, or safety of the facility.

(2) *Competitive bids.* (i) Obtain the approval of the Secretary before the project is advertised or placed on the market for bidding; such approval must include a determination by the Secretary that the final plans and specifications conform to the standards set forth in §51c.503(a)(7)(iii) of these regulations.

(ii) Except as otherwise provided by State or local law, contract for construction (including the purchase and installation of built-in equipment) on a lump sum fixed-price basis, and award contracts on the basis of competitive bidding obtained by public advertising with award of the contracts to the lowest responsive and responsible bidders. The provision for exceptions based on State and local law shall not be invoked to give local contractors or suppliers a percentage preference over non-local contractors bidding for the same contract. Such practices are precluded by this paragraph.

(3) *Construction contracts.* (i) Include the following conditions and provisions in all construction contracts for the modernization project:

(A) The provisions set forth in "DHHS Requirements for Federally Assisted Construction Contracts Regarding Labor Standards and Equal Employment Opportunities," Form DHHS 514 (rev. 7/76) (issued by the Office of Grants Administration Policy, U.S. Department of Health and Human Services) pertaining to the Davis-Bacon Act, the Contract Work Hours Standards Act, and the Copeland Act (Anti-Kickback) Regulations, except in the case of contracts in the amount of \$2,000 or less; and pertaining to Executive Order 11246, 30 FR 12319 (September 24, 1965), as amended, relating to nondiscrimination in construction contract employment, except in the case of contracts in the amount of \$10,000 or less;

(B) That the contractor shall furnish performance and payment bonds each of which shall be in the full amount of the contract price, and shall maintain, during the life of the contract, adequate fire, workmen's compensation, public liability, and property damage

insurance: *Provided, however,* That in the case of a State or local unit of government which enters into a construction contract of less than \$100,000, State or local provisions with respect to performance and payment bonds shall be deemed to meet the requirements of this paragraph; and

(C) That the Secretary shall have access at all reasonable times to work wherever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

(ii) *Executive Order 11246.* Comply with the applicable requirements of Executive Order 11246, 30 FR 12319 (September 24, 1965) as amended, relating to nondiscrimination in construction contract employment, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

(4) *Modernization supervision.* Provide and maintain competent and adequate architectural or engineering supervision and inspection at the modernization site to insure that the completed work conforms with the plans and specifications.

(5) *Completion responsibility.* Complete the modernization in accordance with the grant application and the approved plans and specifications.

(6) *Progress reports.* Furnish progress reports and such other information concerning the modernization as the Secretary may require.

(d) The Secretary may at any time approve exceptions to the provisions of this section where he finds that such exceptions are not inconsistent with section 330 of the Act, other requirements of law, or the purposes of the program.

[41 FR 57000, Dec. 30, 1976, as amended at 43 FR 5352, Feb. 7, 1978]

§51c.505 Determination of cost.

The cost of acquisition and/or modernization of existing buildings for which funds may be granted under this part will be determined by the Secretary, utilizing such documentation submitted by the applicant as the Secretary may prescribe (including the reports of such real estate appraisers as the Secretary may approve) and other relevant factors, taking into consideration only that portion of the existing

building necessary for the operation of the approved project.

[41 FR 5700, Dec. 30, 1976]

§ 51c.506 Use of grant funds.

Grant funds may be used to amortize the principal of or pay interest on a loan or mortgage on an existing building acquired under this part, including a building purchased by a grantee prior to the promulgation of this part, but only if the building is being used for the purposes of section 330 and complies with the applicable provisions of this subpart and only to the extent the Secretary finds such principal amounts and interest rates to be reasonable.

[41 FR 5700, Dec. 30, 1976]

§ 51c.507 Facility which has previously received Federal grant.

No grant for the acquisition of a facility which has previously received a Federal grant for construction, acquisition, or equipment shall serve either to reduce or restrict the liability of the applicant or any other transferor or transferee from any obligation of accountability imposed by the Federal Government by reason of such prior grant.

[41 FR 5700, Dec. 30, 1976]

PARTS 51d–51g [RESERVED]

PART 52—GRANTS FOR RESEARCH PROJECTS

Sec.

52.1 To which programs do these regulations apply?

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AUTHORITY: 42 U.S.C. 216.

§ 52.1 To which programs do these regulations apply?

(a) *General.* The regulations of this part apply to all health-related research project grants administered by

the PHS or its components, except for grants for health services research, demonstration, and evaluation projects administered by the Agency for Health Care Policy and Research. These regulations do not apply to research grants that are not for the support of an identified research project (sometimes referred to as general research support grants), grants for the construction or operation of research facilities, grants for prevention or educational programs, demonstration grants, traineeships, training grants, or to the support of research training under the National Research Service Awards program.

(b) *Specific programs covered.* From time to time the Secretary will publish a list of the research project grant programs covered by this part. The list is for informational purposes only and is not intended to restrict the statement of applicability in paragraph (a) of this section. In addition, information on particular research project grant programs, including applications and instructions, may be obtained from the component of the PHS that administers the program.

[61 FR 55105, Oct. 24, 1996.]

§ 52.2 Definitions.

As used in this part:

Act means the Public Health Service Act, as amended (42 U.S.C. 201 *et seq.*).

Grantee means the institution, organization, individual or other person designated in the grant award document as the responsible legal entity to whom a grant is awarded under this part. The term shall also mean the recipient of a cooperative agreement awarded under this part.

HHS means the Department of Health and Human Services.

Principal investigator means a single individual designated by the grantee in the grant application and approved by the Secretary, who is responsible for the scientific and technical direction of the project.

Project means the particular activity for which funding is sought under this part as described in the application for grant award.

Public Health Service and *PHS* means the operating division of the Department that consists of the Agency for